

**REMARKS**

This Application has been carefully reviewed in light of the *Office Action*. At the time of the *Office Action*, Claims 40-44, 46-57, 62, 63, and 65-70 were pending and rejected. Applicants have amended Claims 40, 41, 44, 55, 56, 67, and 70, and added Claims 71 and 72. Applicants respectfully request reconsideration and favorable action in this case.

**Objections to Specification**

The Examiner objects to the specification under 35 U.S.C. § 132 as allegedly containing new matter. Specifically, the Examiner argues “[a]lthough applicant appears to have support for a constant thread height and pitch, applicant does not appear to have support for the term “substantially” constant. Applicants respectfully traverse this objection.

According to the M.P.E.P., “[b]y disclosing in a patent application a device that inherently . . . has a property . . . a patent application necessarily discloses that function, theory or advantage, even though it says nothing explicit concerning it. The application may later be amended to recite the function, theory or advantage without introducing prohibited new matter.” § 2173.07(a).

Applicants respectfully contend one of ordinary skill in the art would appreciate Applicants’ specification supports substantially constant physical characteristics (e.g., thread pitch and the thread height) for example due to manufacturing imperfections or tolerances.

**Objections to Claims**

The Examiner objects to Claim 41 as having improper dependency. See *Office Action*, page 5. In response, Applicants have amended Claim 41 to depend from Claim 40. Consequently, Applicants respectfully request the Examiner to withdraw the objection to Claim 41.

**Section 112 Rejections of Claims 40, 44, 46, 48, 55-57, 62-63 and 65-70**

The Examiner rejects Claims 40, 44, 46, 48, 55-57, 62-63 and 65-70 under 35 U.S.C. § 112, first paragraph, as allegedly failing to comply with the written description requirement. Applicants respectfully traverse those rejections for the reasons stated below.

With respect to Claims 40, 44, 46, 48, 55-57, 62-63 and 65-70, the Examiner asserts that the specification does not have support for “a substantially constant thread height.” More particularly, the Examiner contends that “applicant does not have support for the term

‘substantially’ which broadens the dimensions to a range such that adjacent threads may have slightly different dimensions.” See *Office Action*, page 4, line 22 - page 5, line 3. However, According to the M.P.E.P., “[b]y disclosing in a patent application a device that inherently . . . has a property . . . a patent application necessarily discloses that function, theory or advantage, even though it says nothing explicit concerning it. The application may later be amended to recite the function, theory or advantage without introducing prohibited new matter.” § 2173.07(a).

Applicants respectfully contend one of ordinary skill in the art would appreciate Applicants’ specification supports substantially constant physical characteristics (e.g., thread pitch and the thread height) for example due to manufacturing imperfections or tolerances. Consequently, Applicants respectfully request the Examiner to withdraw the associated rejections of Claims 40, 44, 46, 48, 55-57, 62-63 and 65-70, under 35 U.S.C. § 112, first paragraph.

### **Section 102 Rejections**

The Examiner rejects Claims 40, 41, 52, 53, 55, 56, 62, and 66 under 35 U.S.C. § 102(b) as allegedly being anticipated by U.S. Patent No. 5,607,304 (“*Bailey*”). The Examiner further rejects Claims 40, 41, 47, 50, 52-56, 62, 63, 66, and 70 under 35 U.S.C. § 102(b) as allegedly being anticipated by U.S. Patent No. 5,683,460 to Persoons (“*Persoons*”). Applicants respectfully traverse those rejections for the reasons stated below.

#### **I. *Bailey* fails to disclose a “headless” body as recited in Claim 40.**

Claim 40, as amended, recites “[a] medical implant, comprising . . . a headless body.” The Examiner rejects the unamended version of Claim 40 by pointing to a medical implant illustrated in Figures 1 and 2 of *Bailey*. See *Office Action*, page 5, lines 13-16. However, Applicants respectfully contend that the alleged medical implant of *Bailey* does not disclose a headless body. Rather, as shown in Figures 1 and 2, the threaded portion of the medical implant of *Bailey* is coupled to a “shoulder 42.” Consequently, *Bailey* fails to disclose a headless body as recited in Claim 40. For at least those reasons, Applicants respectfully contend that Claim 40 and its dependent claims (e.g., Claims 41-43, 46-54, and 72) are allowable over *Bailey*. For analogous reasons, independent Claims 55 its respective dependent claims (e.g., Claims 56-57, 62-63, and 65-66) are allowable over *Bailey*.

**II. *Persoons* fails to disclose the limitations “the leading flank separated from the trailing flank by a narrowing clearance therebetween” as recited in Claim 40.**

The Examiner also rejects the unamended version of Claim 40 by pointing to a medical device illustrated in Figure 2 of *Persoons*. See *Office Action*, page 6, lines 5-21. However, Claim 40, as amended, recites “[a] medical implant . . . wherein . . . the thread includes a leading flank spanning from the crest to a thread root and a trailing flank spanning from the crest to the thread root, the leading flank separated from the trailing flank by a narrowing clearance therebetween.” *Persoons* fails to disclose those limitations at least because the alleged “flanks” on the thread of *Persoons* (i.e., the sides of thread 105 see *Office Action*, page 6, lines 20-22) are not separated by a “narrowing clearance” as recited in Claim 40. See e.g., *Persoons*, Figure 2.

Furthermore, *Persoons* explains with respect to the distance between the sides of its thread, “[t]he peg includes . . . between substantially radially protruding first and second sequential members, a first notch **intended for housing the posterior cortical wall** of the metaphysis of the radius.” *Persoons*, Col. 1, lines 41-46 (emphasis added). Since *Persoons* explains that the intended purpose of the notch between the thread is to house the cortical wall of the metaphysis of the radius, one would not be motivated to modify the threading on the medical device of *Persoons* to include “a narrowing clearance therebetween” because such a modification would render the thread inoperable for its intended purpose of housing the posterior cortical wall. See *Persoons* Col. 1, lines 39-49; see also Figure 2. For at least those reasons, Applicants respectfully contend that Claim 40 and its dependent claims (e.g., Claims 41-43, 46-54, and 72) are allowable over *Persoons*. For analogous reasons, independent Claims 55 and 70 their respective dependent claims (e.g., Claims 56-57, 62-63, and 65-66 and Claim 71) are allowable over *Persoons*.

**Section 103 Rejections**

The Examiner, under 35 U.S.C. § 103(a), rejects as allegedly being unpatentable: Claims 43, 46, 48, 49, 50, 51, and 65 over *Bailey* in view of the knowledge of one of ordinary skill in the art, Claims 40, 41, 43, 50, 52, 53, 55, 56, 62, and 66 over U.S. Patent No. 5,961,524 to Crombie (“*Crombie*”) in view of the knowledge of one of ordinary skill in the art, Claims 42, 44, and 57 over *Persoons* in view of U.S. Patent No. 5,951,560 to Simon et al.

(“*Simon*”), and Claims 67-70 over U.S. Publication No. 2004/0097928 A1 by Zdeblick et al. (“*Zdeblick*”) in view of U.S. Patent No. 5,897,593 to Kohrs et al. (“*Kohrs*”). Applicants respectfully traverse those rejections for the reasons stated below.

**III. *Crombie* fails to disclose a “headless” body as recited in Claim 40.**

Claim 40, as amended, recites “[a] medical implant, comprising . . . a headless body.” The Examiner rejects the unamended version of Claim 40 by identifying an “entire screw 10” in *Crombie* as the body of Claim 40. See *Office Action*, page 7, lines 20-23. However, Applicants respectfully contend that the screw of *Crombie* does not disclose a headless body. Rather, as shown in Figures 1 and 2, the threaded portion of the medical implant of *Crombie* is coupled to a screw head. Consequently, *Crombie* fails to disclose a headless body as recited in Claim 40. For at least those reasons, Applicants respectfully contend that Claim 40 and its dependent claims are patentable over *Crombie*. For analogous reasons, independent Claim 55 its respective dependent claims are allowable over *Crombie*.

**IV. *Persoons* fails to disclose the limitations “the distance between the leading flank and the trailing flank narrowing as one moves from the crest toward the thread root” as recited in Claim 44.**

Claim 44, as amended, recites “[a] medical implant . . . wherein . . . the thread includes a leading flank spanning from the crest to a thread root and a trailing flank spanning from the crest to the thread root, the leading flank separated from the trailing flank by a narrowing clearance therebetween.” The Examiner rejects the unamended version of Claim 44 by pointing to the medical device illustrated in Figure 2 of *Persoons* in view of the medical device of *Simon*. See *Office Action*, page 8, line 15 - page 9, line 6. However, as explained with respect to Claim 40 above, *Persoons* fails to disclose the above-quoted limitations at least because the alleged “flanks” on the thread of *Persoons* (i.e., the sides of thread 105 see *Office Action*, page 6, lines 20-22) are not separated by a “narrowing clearance” as recited in Claim 40. See e.g., *Persoons*, Figure 2.

Furthermore, *Persoons* explains with respect to the distance between the sides of its thread, “[t]he peg includes . . . between substantially radially protruding first and second sequential members, a first notch **intended for housing the posterior cortical wall** of the metaphysis of the radius.” *Persoons*, Col. 1, lines 41-46 (emphasis added). Since *Persoons* explains that the intended purpose of the notch between the thread is to house the cortical

wall of the metaphysis of the radius, one would not be motivated to modify the threading on the medical device of *Persoons* to include “a narrowing clearance therebetween” because such a modification would render the thread inoperable for its intended purpose of housing the posterior cortical wall. See *Persoons* Col. 1, lines 39-49; see also Figure 2. For at least those reasons, Applicants respectfully contend that Claim 44 is allowable over *Persoons* in view of *Simon*.

**V. *Zdeblick* fails to disclose “at least one continuous and uninterrupted thread . . . helically traversing a length of an exterior surface of the body, the length spanning from the first end to the second end” as recited in Claim 67.**

Claim 67, as amended, includes the limitations, “the body comprising . . . at least one continuous and uninterrupted thread including . . . a crest with a substantially flat surface and having a substantially constant thread height and helically traversing a length of an exterior surface of the body, the length spanning from the first end to the second end.” The Examiner rejects the unamended version of Claim 67 by pointing to “thread 19” on a “fusion device 10” illustrated in Figure 2 of *Zdeblick*. See *Office Action*, page 9, lines 9-19. However, Applicants respectfully point out that thread 19 of *Zdeblick* does not span from the first end to the second end of the alleged body of *Zdeblick*. See e.g., *Zdeblick*, Figure 2. For at least those reasons Applicants respectfully contend that *Zdeblick* fails to disclose “[a] medical implant, comprising . . . at least one continuous and uninterrupted thread including . . . a crest with a substantially flat surface and having a substantially constant thread height and helically traversing a length of an exterior surface of the body, the length spanning from the first end to the second end” as recited in Claim 67. Accordingly, Applicants respectfully contend that independent Claim 67 and its dependent claims (e.g., Claims 68-69) are allowable over *Zdeblick* in view of *Kohrs*. For analogous reasons, independent Claim 70 and its dependent claim, Claim 71, are allowable over *Zdeblick* in view of *Kohrs*.

**No Waiver**

Applicants have merely discussed example distinctions from the references cited by the Examiner. Other distinctions may exist, and Applicants reserve the right to discuss those additional distinctions in a later Response or on Appeal, if appropriate. By not responding to additional statements made by the Examiner, Applicants do not acquiesce to the Examiner’s

additional statements. The example distinctions discussed by Applicants are sufficient to overcome the Examiner's rejections.

**All Claims Are in Condition for Allowance**

For at least the reasons explained above, Applicants respectfully contend that each and every one of the claims of the instant Application are in condition for allowance. Moreover, Applicants respectfully contend that none of the deficiencies explained above are accounted for by the teaching of any of the remaining references. Applicants respectfully request allowance of all pending claims.

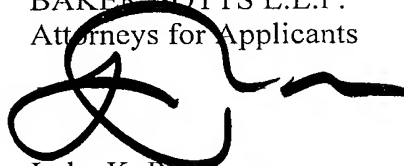
CONCLUSION

Applicants have made an earnest attempt to place this case in condition for allowance. For the foregoing reasons, and for other apparent reasons, Applicants respectfully request full allowance of all pending Claims. If the Examiner feels that a telephone conference or an interview would advance prosecution of this Application in any manner, the undersigned attorney for Applicants stand ready to conduct such a conference at the convenience of the Examiner.

Applicants believe no fee is due. However, if a fee is required, the Commissioner is hereby authorized to charge any fees or credit any overpayments to **Deposit Account No. 02-0384 of Baker Botts L.L.P.**

Respectfully submitted,

BAKER BOTTS L.L.P.  
Attorneys for Applicants



Luke K. Pedersen  
Reg. No. 45,003

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CORRESPONDENCE ADDRESS:

Customer Number:

05073